## Remarks

Claims 26-53 are pending. Favorable reconsideration is respectfully requested.

Claim 26 has been amended to recite that there are from 1-10 formamide groups present in the formamide compound, combining the former limitations of claim 27 into claim 26. Claim 27 has been amended to recite preferred formamides where n is 1 to 5, support for which may be found on page 4, last paragraph, of the specification. New claim 53 has been added to claim preferred substrates where R is a  $C_{6-30}$  aryl group or a formamide of a polyphenylenepolymethylenepolyamine, support for which may be found on page 4 of the specification. No new matter is added by virtue of these claim amendments.

Claims 26, 37, 46, 48, 50, and 52 have been rejected under 35 U.S.C. § 112, ¶ 1, as set forth in the Office Action on pages 2-5. Applicant respectfully traverses these rejections, as discussed below. At the outset, it must be remembered that the specification and claims are directed to one of ordinary skill in the art.

The Office has objected, apparently, to the breadth of the claims, as claim 26 prior to amendment did not limit the number of isocyanate groups. Claim 26 has been amended such that from 1 to 10 formamide groups, and hence from 1 to 10 isocyanate groups are claimed. The claim is thus believed to cover all commercial embodiments, although there is no reason to suspect that 12 or 20 formamide groups, and hence isocyanate groups, would not also be operable.

The Office has cited the so-called "Wands" or "Forman" factors in alleging non-enablement. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988); *Ex parte Forman*, 230 USPQ 546 (BPA1 1986). Both these case are directed to the complex field of biotechnology, where, at the time of filing the applications, the fields of gene splicing, cloning, hybridization, etc., were still somewhat unpredictable. However, even in the face of this unpredictability, the Court in *Wands* reversed the Examiner and the Board, despite the fact that the actual examples of *Wands* were only limited to an exceptionally small subset of the subject matter

claimed. As explained by the Court, it is not the number of actual examples or even unpredictability which is at issue. Rather, the question is whether one skilled in the art could practice the claimed invention without undue experimentation. Despite the exceptionally unpredictable nature of the subject matter, the Court found that experimentation was not undue, even though it might be "considerable." *Wands* at 1404, citing *Ansul v. Uniroyal*, 169 USPQ 759 (2nd Cir. 1971). Here, complex biotechnology is not involved, but rather organic chemistry.

The standards for enablement are well set forth in numerous precedents, which continue to be the law, unless overruled by the Federal Circuit *en banc*. In the case of *In re Marzocchi*, 169 USPQ 367 (CCPA 1971), the Court plainly and unequivocally indicated that the law requires no more than objective enablement to satisfy 35 USC § 112, ¶ 1, whether achieved by illustrative examples or by broad terminology. *Marzocchi* also indicates that the specification is <u>presumptively</u> accurate.

The Examiner has set forth no evidence based on sound scientific reasoning, nor an affidavit under 37 CFR § 1.107(b), as to why the full scope of the claims is not enabled. An assertion that the presumptively enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts expressed. *In re Dinh-Nguyen*, 181 USPQ 46 (CCPA 1974); *In re Bown*, 181 USPQ 48 (CCPA 1974); *In re Armbruster*, 185 USPQ 152 (CCPA 1975).

In the case of *In re DiLeone*, in response to the position taken by the Examiner and by the Board that in order to "justify" or "support" a broad generic claim, the specification had to be equally broad in its naming and use of examples, the Court stated:

Mention of representative compounds encompassed by the generic claim language clearly is not required by Sec. 112 or any other provision of the statute.

\* \* \*

Similarly, representative examples are not required by the statute, and are not an end in themselves.

In re DiLeone, 168 USPQ 592 (CCPA 1971).

The Board has also addressed enablement on several occasions. For example, in *Ex parte Friedman*, 136 USPQ 381, the Board stated that the Examiner's "unsupported skepticism" that starting materials might not work is insufficient to require the Applicant to limit process claims to the specific reactants disclosed.

The mere conclusory statement that "more than routine experimentation is required" does not meet the above requirements. Furthermore, "routine" is not the legal standard. The legal standard is "undue experimentation," which allows for "considerable experimentation." Wands at 1404. Here, one skilled in the art can readily assess the workability of any formamide or amine precursor, catalysts, etc., by simple, routine (not even "considerable") experimentation. There is no question but that the claim scope is fully enabled. Withdrawal of the rejections on this basis is solicited.

Specifically, with respect to the number of formamide groups, while Applicant believes that all numbers of formamide groups are enabled, Applicant has amended the claims to from 1 to 10 groups, which the Examiner agrees is enabling (Office Action, p. 3,  $\P$  2).

With respect to diorganocarbonates, Applicant is puzzled, since the claims are limited to diaryl carbonates and mixed aliphatic/aryl and cycloaliphatic/aryl carbonates. Support is found in the specification, thus meeting the requirements for enablement as set forth by *Marzocchi*. Dimethylcarbonates, di(n-propyl)carbonates, etc., are <u>not</u> within the scope of the claims.

The specification provides a broad description of suitable amines, and the Office has not set forth evidence of why any particular organic amine would be inoperable.

Suitable metal catalysts are set forth in the specification and are well known to those skilled in the art. Furthermore, whether a particular catalyst is useful can be easily ascertained by simple experiments comparing the rate of reaction and yield to other catalysts. No undue experimentation is required. Withdrawal of all rejections under 35 USC § 112, ¶ 1 is solicited.

Certain claims (26, 27, 28, 31, 33, 37, and 42) have been rejected under 35 USC § 112, ¶ 2. Applicant respectfully traverses these rejections.

For claim 26 "elevated temperature" is not the entire claim limitation. The term is "elevated temperature (i.e. above standard temperature, 25°C) sufficient to generate the isocyanate corresponding to said organic formamide compound." Examples of suitable ranges are given in the specification and examples. The actual temperature will depend upon the particular formamide, presence or absence of catalyst, etc., and thus it is impossible to specify a distinct temperature. The temperature at which isocyanate formation occurs can be easily determined. The claim is not indefinite.

Claim 27 requires R to be "an organic radical." This term is defined on page 5, and numerous examples are given. One skilled in the art, to which the claims are addressed, has no difficulty of ascertaining the scope of the claim. The claim is definite to one skilled in the art.

Claim 28 indicates that R may contain one or more hetroatoms. One skilled in the art is aware of what hetroatoms are useful. The most common hetroatoms are O, S, N, P, and B. "Hetroatom" is used by organic chemists to indicate a ring or chain atom other than carbon. Examples of ring hetroatom radicals include pyridyl and quinolyl which are disclosed in the specification. To one skilled in the art, the claim is definite. The Office has supplied no evidence to suggest otherwise.

Claim 31 includes the phrase "at a temperature wherein isocyanate is produced." This term is clear on its face. The actual temperature will depend in any specific case on the nature of the formamide, etc. The claim is definite.

Claim 33 requires performing the reaction at a first temperature below 190°C and where substantially no isocyanate is produced, and then thermolyzing this reaction mixture at a second, higher temperature, to obtain the isocyanate. Since isocyanate is obtained, the second temperature is clearly a temperature at which isocyanate is produced, a temperature easily measured. The claim is definite.

Claim 37 requires "an effective carbamide-cleaving amount of a metal catalyst." The Office alleges this to be indefinite "where the claim fails to state the function which is to be rendered effective." The claim language already includes this function: "carbamide-cleaving." The claim is definite.

For claim 32, hetroatoms and substituents are defined on page 5 beginning at line 12 and continuing to page 6, line 16. The claim is definite. Withdrawal of all the rejections of the claims under 35 USC § 112, ¶2 is solicited. If any rejection is to be maintained, sound reasoning supported by appropriate citations must be supplied with respect to each rejection rather than a conclusory allegation of indefiniteness. Otherwise, a *prima facie* case is not established.

Claims 26 - 52 have been rejected under 35 U.S.C. § 103(a) over Okawa, U.S. Patent No. 5,166,414 ("Okawa") in view of Kober et al., U.S. Patent No. 3,366,662 ("Kober"), further in view of Faroj, U.S. Patent No. 5,686,675 ("Faraj"). Applicant respectfully traverses this rejection.

Faraj is apparently cited to show that the bis(N-formamide) of toluene diamine is a known compound, and Applicant has admitted on the record that this is the case. Applicant believes that this compound has been known for many, many years. However, the process of Faraj has nothing in common with the present invention. Faraj teaches

manufacturing isocyanate precursors which are <u>unsymmetrical carbamates and ureas</u> from formamides, dialkylamine, and alcohol, in the presence of a noble metal catalyst. This reaction has nothing in common with that of the present invention. The drawbacks of using noble metal catalysts is discussed in the specification on pages 2 and 3. *Faraj* does not indicate that formamides are isocyanate precursors. Rather, he indicates that unsymmetrical carbonates and ureas are precursors. *Faraj* employs formamides in a highly different reaction than Applicant or, for that matter, either *Kober* or *Okawa*.

Okawa discloses a process for manufacturing isocyanates in a two step reaction. In the first step, which requires catalysis by a basic catalyst, a formamide is reacted with dimethylcarbonate to produce the corresponding urethane compound. The urethane compound is then purified to be free of catalyst and thermolyzed in a high boiling solvent. Methanol and the isocyanate product are separated from the vapor phase.

As an "alternative" process, *Okawa* reacts an amine with methylformate in the presence of dimethylcarbonate and alkali catalyst, apparently generating the respective formamide *in situ*, which then reacts with dimethylcarbonate to produce the urethane. The urethane is then purified, and the catalyst-free urethane is thermolyzed in high boiling solvent.

Kober is a very old reference (1968) which discloses one of a myriad of failed, phosgene-free methods of isocyanate production. Kober reacts one of a select and limited group of organic amines with a diarylcarbonate and distills isocyanate from the reaction mixture. Yields of 55 - 68% are reported. The amines of Kober are limited to alkyl- and arylmonoamines and  $\alpha$ , $\omega$ -alkylenediamines. Glaringly missing from this list are the amine precursors to the most important isocyanates of commerce: diaminodiphenylmethane, toluenediamine, and isophoronediamine. One assumes that the Kober process does not work with such compounds, in particular since Kober specifically mentions the large quantities in which toluene diisocyanate is produced, but fails to indicate that 2,4-toluenediamine could be employed in his process.

The present invention is not disclosed, taught, or suggested by the cited references, either alone or in combination, within the requirements of 35 U.S.C. § 103(a). First, the references are not physically combinable. Second, as indicated in Applicant's last response, there is no motivation to combine the references.

Okawa is directed to a specific isocyanate synthesis process employing a formamide isocyanate precursor and one very specific carbonate, dimethylcarbonate. When Okawa uses his alternative process involving an amine, he further employs methylformate, which reacts with the amine to produce the respective formamide in situ. In both processes, a byproduct is easily vaporizable methyl alcohol, in the preferred process being derived from the dimethylcarbonate, and in the alternative process, being derived both from the methyl formate as well as the dimethylcarbonate.

Okawa does not disclose any other carbonate as being useful in his process, although a myriad of organic carbonates have been known and commercially available for many years, and were certainly known to Okawa. One reason for this is clearly connected with Okawa's process, in which following purification and separation of catalyst, the Omethyl-carbamate (methyl urethane) product is pyrolyzed in high boiling solvent to generate a vapor of methanol and isocyanate, from which the latter is fractionally condensed. Higher alkyl and particularly aryl carbonates would not work in such a process, as the boiling points of the respective alcohols which would be liberated are too high to effect efficient separation, and as indicated by Okawa and discussed later, would lead to polymerization of the isocyanates, i.e. xylylene isocyanate, which Okawa produces.

While *Okawa* indicates that "aromatic" formamides are useful in his process, the "aromatic" formamides he discloses are not truly aromatic, but rather are aliphatic formamides where the formamide group is separated from the aromatic ring system by an intervening alkylene group. An example is the bis(formamide) of xylylene diamine, where the formamide group is bonded to a methylene group which is then bonded to the benzene ring.

Applicant has tested the ability of dimethylcarbonate to react with aromatic substrates, such as the bis(formamide) of 2,4-toluene diamine. At 150°C, no reaction occurs if uncatalyzed. If catalyzed by basic catalysts such as 4-(N,N-dimethylamino)pyridine, a variety of N-methylated products are obtained; no dicarbamates are produced. With NaOCH<sub>3</sub> as the basic catalyst, again, N-methylated products are produced. A declaration pertaining to these results will be submitted under separate cover. Thus, the reason *Okawa* discloses any aliphatic formamides is that his reaction only appears to work with such aliphatic compounds, and requires a catalyst even then.

Diametrically opposed to *Okawa* is *Kober*. *Kober* does not teach the reaction of formamides with dimethylcarbonate. Factually, *Kober* does not react or produce formamides. *Kober's* reactants are amines and diarylcarbonates. When *Kober* uses amine reactants, he does not use the required methylformate required by *Okawa*. Thus, the reaction of *Kober* is completely different from that of *Okawa*.

With respect to the organic carbonate employed by *Kober*, he is quite specific, preferring diphenylcarbonate, and disclosing only halogenated diarylcarbonates in addition to the preferred diphenylcarbonate. Thus, while *Okawa* requires dimethylcarbonate and fails to mention any other carbonates, *Kober* uses diarylcarbonates and fails to mention a single aliphatic carbonate. The respective teachings relating to the organic carbonate are diametrically opposed. The references cannot be physically combined for this reason. To simply take the diphenylcarbonate of *Kober* and substitute it for the dimethylcarbonate of *Okawa* would make the *Okawa* process unworkable. *Okawa* requires separating isocyanate product from a vapor stream of methanol and isocyanate, due to the low boiling point of methanol. If diphenylcarbonate were substituted for dimethylcarbonate, phenol, a much higher boiling alcohol (about 120°C higher) would be liberated during the course of the reaction rather than methanol.

The reactions in *Okawa* and *Kober* are also very different. *Okawa* reacts a formamide, prepared separately, or *in situ*, with dimethyl carbonate. *Kober* does not do so. *Kober* reacts an amine with a diarylcarbonate. *Kober* does not employ any formamide. The

starting materials of *Okawa* and *Kober* are completely different. In *Okawa's in situ* process, the formamide is generated by reaction of an amine with methylformate. *Okawa* states that reaction of amine with methylformate is rapid, and thus it is the *in situ*-produced formamide, and not the amine which reacts with dimethylcarbonate. *See Okawa* at column 3, line 62 to column 4, line 9 and column 4, lines 29 - 41. Because the starting materials are chemically different, *Okawa* chose dimethylcarbonate as the sole organic carbonate in his process, while *Kober* chose a diarylcarbonate in his very different process. To combine these references would require picking and choosing only selected portions of the reference disclosure (i.e. diphenylcarbonate) while ignoring other salient features (such as *Kober's* different starting materials). To pick and choose in this manner is improper, and cannot be used to support a rejection under 35 U.S.C. § 103(a). *In re Wesslau*, 147 U.S.P.Q. 391 (CCPA 1965).

There is no motivation to combine these references. The Federal Circuit has recently addressed the quantum of evidence required to support an allegation of motivation to combine references.

In the case of *In re Anita Dembiczak* and *Benson Zinbarg*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999), the CAFC has indicated that the requirement for showing the teaching or motivation to combine references is "rigorous." *Dembiczak* at 1617. Moreover, this showing, which is rigorously required, must be "clear and particular." *Dembiczak* at 1617. See also, *C.R. Bard v. M3 Sys., Inc.*, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998). It is well established that merely because references can be combined, the mere suitability for logical combination does not provide motivation for the combination. See, *Berghauser v. Dann, Comr. Pats.*, 204 U.S.P.Q. 398 (DCDC 1979); *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984). Moreover, mere conclusory statements supporting the proposed combination, standing alone are not "evidence". *McElmurry v. Arkansas Power & Light Co.*, 27 U.S.P.Q.2d 1129, 1131 (Fed. Cir. 1993). *See also, In re Lee*, 61 U.S.P.Q. 2d 1430 (Fed. Cir. 2002).

Here, while the aim of both references is to provide a non-phosgene process for isocyanate production, there the similarity stops. *Okawa* discloses a specific process for

preparation of isocyanates where the isocyanate is separated from a vapor phase of methanol/isocyanate. One skilled in the art would not be motivated to substitute a diarylcarbonate for the dimethylcarbonate of *Okawa*, since by so doing, the entire process disclosed by *Okawa* would be rendered inoperative. There would be no methanol/isocyanate vapor phase, nor any equivalent vapor phase containing an isocyanate and a low boiling solvent derived from an organic carbonate. One would further not be motivated to make this substitution since neither reference suggests doing so. Factually, since the respective reactions are different, and because each reference is directed only to a specific class of organic carbonates with no mention of any organic carbonates of the other class, there is a complete lack of any evidence of motivation to combine, much less any evidence which rises to the clear and particular standard required by Dembiczak.

The Examiner's arguments presented in the last response are noted. However, it is respectfully submitted that these arguments are fatally flawed. The Examiner states, for example, with respect to *Okawa* and *Kober*, that "[t]heir reaction processes share a common reaction mechanism with either dimethylcarbonate or diphenyl carbonate belonging to commonly known organic carbonates. Furthermore, the *Okawa* reference does indicate the equivalency between the use of formamide compound and the amine compound in the reaction process." These statements are wrong.

First, *Okawa* nowhere "equates" amines with formamides. The statement cited by the Examiner is taken out of context. At column 5, lines 1-5, *Okawa* states:

While aliphatic diisocyanate compounds with a high added value can be obtained from these compounds, the process of the present invention makes it also possible to produce aromatic diisocyanate compounds with a high versatile utility from aromatic diamine compounds.

This statement refers to the foregoing paragraph at column 4, lines 63-68.

In the second aspect of the present invention, on the other hand, aliphatic amine compounds are preferably used as the principal starting material. Particularly advantageously used among them are — and p-xylylenediamine, N, N'-[1,3-cyclohexylbis(methylene)]-bisamine and its 1,4-isomer.

This paragraph references the <u>starting</u> material precursors, which are readily available, and are <u>first converted to the corresponding formamides</u> for use in the process of *Okawa*. The conversion of the amine precursor to the formamide is accomplished by reaction with methylformate, as illustrated by Example 1, where xylylene diamine, an aliphatic diamine, is reacted with methylformate and the methanol distilled to form the bis(formamide) of xylylene diamine. In Example 7, the formamide is prepared *in situ*. In either case, it is clear from *Okawa* that it is the <u>formamide</u> which reacts, <u>not the amine</u>. Otherwise, why go to the trouble of preparing the formamide at all? The <u>entire</u> disclosure of *Okawa* is directed to reacting a <u>formamide</u> with methyl carbonate, <u>not</u> an amine.

Kober, on the other hand, does not employ a formamide at all. Kober does not employ any methyl formate, or any other reagent which produces a formamide, either separately or in situ. Kober directly reacts an amine with diphenyl carbonate.

The Examiner states that the reaction mechanism is the same because *Kober* and *Okawa* both employ carbonates. There is <u>no</u> support for this assertion. The reaction mechanisms <u>cannot</u> be the same, since the reactants are chemically distinct. Chlorination of hydrocarbons and chlorination of water supplies do not have the same mechanism merely because both use chlorine.<sup>1</sup>

Okawa reacts a <u>formamide</u> with dimethyl carbonate, while Kober reacts an <u>amine</u> with an aryl carbonate. One skilled in the art would <u>not</u> be motivated to employ Kober's aryl carbonate in Okawa's process because first, the reactions and reaction mechanism are

An analogy which is even further removed from the present case, where *Okawa's* process is limited to one very specific aliphatic carbonate, methyl carbonate, while *Kober's* employs aryl carbonates, very distinct species in their reactivities and physical properties.

completely different, and second, to do so would be <u>completely</u> at odds with the purpose of *Okawa*, to be able to remove methanol, a byproduct of his reaction, together with easily polymerizable arylaliphatic isocyanates, at a low temperature. For this reason, *Okawa* limits his carbonate to dimethyl carbonate. *Okawa* does not even suggest using diethylcarbonate or dipropyl carbonate, as the temperature required for separation of the byproduct alkanol would be too high. One reading *Okawa* would be motivated <u>against</u> even using an aliphatic carbonate derived from a higher boiling alkanol, much less an aryl carbonate where the boiling point of the phenol (aryl) obtained would be so much higher.

The reactions of *Okawa* and *Kober* are completely different. They do not share a common mechanism. If the Examiner is to persist in the rejection of the claims over *Okawa* in view of *Kober*, he must supply a reference which indicates that the reaction mechanism used by the two very different processes are the same, or supply an affidavit to that effect. In the absence of such evidence, there is clearly no motivation to combine *Okawa* and *Kober* in the manner suggested. The evidence of record supports the <u>non</u>-combinability of the references, far from the standards required by *In re Dembiczak*. One cannot take isolated teachings from the references and substitute one for another without motivation to do so. *In re Wesslau*, 147 USPQ 391 (CCPA 1965). Here, the reactions are totally different, requiring different starting materials, and the reaction mechanism is *a fortiori* different as well. *Okawa* himself would direct the skilled artisan <u>away</u> from the very change the Office proposes. Withdrawal of the rejection over *Okawa* in view of *Kober* and *Faraj* is solicited.

## Further comments in the Office Action are noted:

Page 8, ¶ 2, "[2,4-bis(N-formamide) of toluene diamine] is well-known to be used as a reactant in the synthesis of isocyanate precursors." This may be so, in the process of Faraj. However, that is not the process claimed, nor is it in any way similar to the process claimed. Faraj employs a completely different reaction, reaction of a formamide with a dialkyl amine or alcohol to form an unsymmetrical carbamate or urea. Faraj does not react a formamide with an aryl carbonate. The "teachings" of Faraj are limited to establishing the

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existence of the formamide of toluene diamine. He does not suggest its use in any other

process.

With respect to absence of a catalyst (page 8, ¶ 3), the Examiner is incorrect

that a catalyst merely speeds up the reaction. In many cases, the reaction simply does not

proceed at all without a catalyst. For example, with aryl amines and dimethyl carbonate, no

reaction occurs at 150°C without a catalyst. It is for this reason even when using more

reactive aliphatic amines, Okawa requires a strongly basic catalyst. Applicant has also shown

that when using aryl amines, even with Okawa's catalyst, no O-carbamates are formed, which

will be included in the upcoming Declaration. Okawa clearly requires a catalyst. It is clearly

unobvious to proceed without one. An unexpected result does indeed occur; the reactants react

even without the catalyst.

With respect to recycling of phenol formate ester, it is true that this is an

optimization. However, an optimization is patentable unless the prior art teaches or suggests

the particular means used to optimize the process. There are many ways to optimize, including

selection of temperature, pressure, catalyst, reactant ratios, type of apparatus, etc. Applicant

finds no suggestion or even the mention in the prior art to optimize by recycling phenol

formate ester. To render this optimization unpatentable, a reference teaching must be supplied.

Applicant submits that the claims are now in condition for Allowance, and

respectfully request a Notice to that effect. If the Examiner believes that further discussion

will advance the prosecution of the Application, he is highly encouraged to telephone Appli-

cant's attorney at the number given below.

Respectfully submitted,

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## ERSION WITH MARKINGS TO SHOW CHANGES MADE

- 26. (Amended) A process for the preparation of organic isocyanates, said process comprising:
  - a) forming a reaction mixture by mixing an organic formamide compound or its amine and formate precursors with at least one diorganocarbonate selected from the group consisting of diarylcarbonates, mixed aliphatic/aryl-carbonates and cycloalphatic/aryl-carbonates;
  - b) subjecting said reaction mixture to an elevated temperature sufficient to generate the isocyanate corresponding to said organic formamide compound; and
  - c) isolating said isocyanate from said reaction mixture; wherein said organic formamide compound is one of the formula

## R+NHCHO)<sub>n</sub>

where n is an integer from 1 to 10 and R is an organic radical.

Attachment Page 1